Before the
FEDERAL COMMUNICATIONS COMMISSION
WASHINGTON, D.C. 20554

In the Matter of	)	
	)	
Investigation of the Spectrum Requirements for Advanced Medical Technologies	)	ET Docket No. 06-135
	)	
Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radio Communications Service at 401-402 and 405-406 MHz	)	RM-11271
	)	ET Docket No. 05-213
DexCom, Inc. Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules	)	ET Docket No. 03-92
	)	
Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules		

COMMENTS OF PARTNERS HEALTHCARE SYSTEM, INC.

INTRODUCTION

Partners HealthCare System, Inc. wishes to thank the Commission for providing the opportunity to comment in the matters of the Dockets listed. We find the Commission's investigation and rulemakings to be both timely and critical to the advancement of the medical arts.

Partners HealthCare System, Inc. (Partners) was founded in 1994 by Brigham and Women's Hospital and Massachusetts General Hospital. Partners is an integrated health care system that offers patients a continuum of coordinated high-quality care. The system includes primary care and specialty physicians, the two founding academic medical centers, community and specialty hospitals, home

health and long-term care services, and community health centers. In addition to its patient care mission, Partners is one of the nation's premier biomedical research organizations and a major teaching affiliate of Harvard Medical School. Partners is a non-profit organization supported in part by charitable contributions.

As a healthcare system, Partners is in the unique position of being both a consumer and provider of advanced medical technologies addressing the many needs of our patients. We therefore find ourselves advocating in behalf of our selves, our patients, and the public in general. We offer general comments reflecting the current and extrapolated future needs for technologies required to address the healthcare needs of our patients and base them upon past experience with wireless communications technologies regulated by the Commission. We also offer specific comments to the Commissions request for information on individual paragraphs of the Commission's Docket 06-103.

GENERAL COMMENTS

As a large healthcare provider, Partners is continuously researching, adopting, and deploying new wireless technologies for use within our healthcare facilities, as well as in the surrounding communities and our patient's homes. Like the Commission members, we see an increasing need to integrate wireless communications system within medical devices. Our experience with devices operating in WMTS, ISM, and Part 15 allocations show that while spread spectrum communications protocol are resistant to interference, they are not interference-proof. We have been able to demonstrate that some communications protocol cause harmful interference with others in both the WMTS and the 2.4 GHz ISM band. To

mitigate this problem, we actively manage the types and numbers of devices operating on our WMTS and WiFi LANs. Currently, several of our WMTS systems are at maximum capacity and we realize that with unrestricted use, the WiFi LANs will soon reach capacity. We agree with the petitioners and Commission that new spectrum needs to be found for the safe operation of medical devices.

Many of the proposed uses of wireless technologies mentioned by the Commissioners in both the NOI and their individual statements involve medical devices with functions critical to the health and well-being of the person using the device. Failure of the communications link in these anticipated systems could expose the user to the risk of injury or death, giving an entirely new meaning to the Commission's definition of "harmful interference." We find it noteworthy the Commission cites the creation of the Wireless Medical Telemetry Service (WMTS) as a direct result of harmful interference to medical telemetry and that the Commission seeks comment regarding the protection of both radionavigation services in the 90-110 kHz band and COSPAS-SARSAT satellite receivers in the 406-406.1 MHz band. In each case, the Commission acknowledges the risk to life if these services suffer interference, yet whether due to conscious decision or a simple oversight, the Commission fails to express the same concern for the proposed medical service. We agree with the Commission's concerns relative to the previously mentioned services and strongly recommend the Commission adopt a similar view toward the protection of the proposed medical device service. We feel the Commission should consider ramifications to the health and safety of patients and individuals, and create primary status allocations for medical device use that affords them regulatory protection from other sources of interference.

Partners' work with medical and consumer device manufacturers also points

to a problem faced by the Commission in regulating the proposed medical device service; when the safe functioning of a medical device relies on the proper functioning of an integral wireless communications circuit, regulation of RF componentry will be equivalent to regulation of the medical device itself. As we see from the statements and replies from the petitioning medical device manufacturers, this puts the Commission in the awkward position of approving or disapproving new medical technologies and devices, which is beyond the scope of the Commission and lies instead with the Food and Drug Administration. Partners recommends the Commission establish an advisory panel, similar to those created by FDA, to be composed of staff from FCC, FDA's Center for Devices and Radiological Health, the medical device industry, wireless communications industry, advocates for the public, and representatives from the healthcare/hospital industry. Partners supports FDA in these advisory efforts and would be supportive of the Commission as well. Partners also urges the Commission to align their regulatory practices regarding medical devices with those of FDA to prevent obstructing development of new medical technologies and confusion that may lead to harmful interference.

The Commission also seeks comment on new implant and body-worn medical radiocommunication technologies, how the Commission could anticipate and proactively address the challenging array of RF spectrum issues, and the relative benefits and tradeoffs that should be considered with respect to both licensed and unlicensed approaches to authorizing the operation of these devices. Partners recognizes needs in many different areas from home-based monitoring of chronic illnesses, to closed-loop feedback of drug delivery and therapy, to restoration of normal function of physiologic systems such as vision, hearing, speech, and muscular control, among many others. Given the expected rapid development of

these technologies, we again urge the Commission to create an advisory committee to help keep it abreast of the advances of the medical arts.

Based upon our experience with both the licensed WMTS technologies and unlicensed wireless LAN technologies, we urge the Commission to 1) restrict the proposed allocation to medical devices regulated by FDA, 2) license these devices by rule as with WMTS, and 3) require the creation, adoption, and use of industry standards and communications protocol to minimize harmful interference to life-critical medical devices similar to those utilized by Part 15 devices operating in the ISM band. Partners is seeing an ever-increasing number of devices and applications developed for use in the ISM bands occupied by unlicensed wireless systems. Some of these system use proprietary protocol that do not coexist with standardized protocol such as IEEE 802.11, and simply serve to cause interference to other systems. To prevent the proliferation of devices that may measure physiological parameters but do not contribute to the diagnosis, management, or therapy of disease and injury, the Commission should limit the approval of new technologies to the proposed allocations to those devices regulated by FDA. We recommend the Commission license such devices by rule, again as they chose to do with WMTS, as this provides a degree of protection as a licensed service should intentional interference occur.

One lesson learned from current wireless technologies is that industry standard communication protocols are important whenever a number of devices are to operate in proximity to one another. Though there are only a handful of telemetry systems approved for operation in the WMTS allocations, each uses a proprietary protocol and as a result, there have been numerous examples of harmful interference between them. In contrast, the IEEE 802.11 FH/a/b/g, Bluetooth, and

other industry standard protocol, behave much more predictably in proximity to one another. While we have observed some interference problems with unlicensed devices operating in beyond manufacturers' recommendations, we are still able to operate them with fewer problems than some of our WMTS equipment. As a result of this experience and the projected growth of wireless medical devices, we urge the Commission to require the development and use of standardized communications protocol for the proposed medical device allocations. We do, however, recognize the significant investment current device manufacturers incurred to bring current devices to market. We therefore urge the Commission to grandfather existing technologies into proposed rulemaking until such time as industry standards can be created and ratified.

Finally, in addition to the advisory panel mentioned earlier, Partners supports collaborative efforts between the Commission and FDA regarding options for better education of not only device manufacturing industry leaders, but also healthcare professionals and the general public, concerning medical radio device electromagnetic immunity issues in an RF environment. In our experience, there is an incredible disparity in the understanding of EMI issues by all parties involved. For example, we have been told by some manufacturers they have "purchased specific frequencies from the FCC for [their] sole use." When inquiring about proprietary protocol to assess for potential interference to other unlicensed systems, we have been informed there was no need to provide the requested information since, "the FCC would not approve any system that could cause interference." There are many other examples of ignorance and misunderstanding on the part of device manufacturers that would be humorous were it not for the seriousness of the ramifications. Further, we realize the Commission knows all too well the degree to

which the general public understands EMI issues, from their dealings with the public regarding interference to consumer devices. Given the expected use of the proposed medical device allocations by the general public in uncontrolled environments, Partners strongly urges the Commission and FDA to create educational websites and conference opportunities not only for the device manufacturers, but for healthcare professionals and the general public as well.

SPECFIC COMMENTS TO PARAGRAPHS OF DOCKETS 06-135, 05-213, 03-92, AND RM-11271

Paragraph 12: As the Commission did with WMTS, Partners urges the Commission to make future medical allocations co-primary in status to protect critical functions of medical devices.

Paragraph 13: The temporary waivers granted by the Commission suffice for today's medical device environment. However, as the numbers of medical devices grow with anticipated use, we believe it possible that harmful interference will become far more likely. We urge the Commission to require device manufactures to develop industry standards, similar to the IEEE 11073 Medical Device Communications efforts, to ensure coexistence between device communications protocol.

Paragraph 15: Partners supports any efforts that could lead to world-wide harmonization of medical device service spectra.

Paragraph 17: Partners supports the new allocations for medical devices for use by consumers, but urges the Commission to work with FDA and ensure the allocation is reserved for regulated medical devices, not consumer appliances and other non-medical equipment.

Paragraph 18: Without passing judgement on the opposition to the proposed rulemaking by DexCom and Biotronik, we see this as another example of the need for the Commission to require industry to develop standards for the use of precious RF spectrum for the critical functioning of medical devices.

Paragraph 19: While we can agree with Biotronik for the time being with respect to the absence of congestion in the MICS band, interest among other companies in developing a myriad of devices to use this spectrum lead us to believe congestion will soon increase to levels where it becomes a significant issue. We urge the Commission to take this into consideration during it's rulemaking.

Paragraph 20: We support the proposed amendments and urge the Commission to license by rule both implanted and "body worn" transmitters for this allocation.

Paragraph 22: While we have no comment upon the emission levels necessary to protect COSPAS-SARSAT operations, we support this effort and recommend the Commission hold a similar view to protecting medical devices in future allocations.

Paragraph 23: While we substantially agree with the Commission's position, we urge the Commission to collaborate with FDA to determine the appropriate level of risk from harmful interference to medical devices whose failure may result in injury or death to the user.

Paragraph 27: We support Medtronic's proposed definition of a body-worn transmitter especially as it requires the transmitter to be part of a medical device regulated by FDA.

Paragraph 29: We strongly disagree with the Commission's position with respect to adopting rules defining operating criteria such as life-critical applications.

The Commission currently enforces such rules, to wit the request for comments in this docket for protection of radionavigation and COSPAS-SARSAT operations. If the Commission determines it is beneficial to the public to create an allocation for life-critical medical devices, they must also be define the rules for minimizing the effects of harmful interference to those devices by ensuring the allocation is properly utilized. We remind the Commission it was a similar line of thinking that led to the creation of unlicensed biomedical telemetry operations under Part 15 on vacant TV channels and the subsequent harmful interference from a new DTV transmitter that further led to the WMTS allocations. The Commission can address it's shortcomings in understanding medical technology by the previously-mentioned collaboration with FDA and advisory panels.

Pargraph 34: Partners supports Guidant's position on the used of devices that produce low-level, incidental radiation in the 90-110 kHz spectrum. Given these devices are operating at low power and not in the vicinity of any radionavigation operations, it is difficult to see why there would be a reason to deny Guidant's proposal. As with Part 15 medical telemetry, the risk of interference is not from the very low-power medical device to the higher-power radionavigation systems, but vice-versa.

With respect to the rest of the Notice of Inquiry, we believe our general comments address most of the Commission's inquiries.

Respectfully submitted,

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